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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 340

[Docket No. APHIS-2006-0124]

RIN 0579-AC08

Sharing Certain Business Information Regarding the Introduction of Genetically Engineered Organisms with State and Tribal Government Agencies

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend our regulations regarding genetically engineered organisms regulated by the United States Department of Agriculture by adding provisions for sharing certain business information with State and Tribal government agencies. The proposed provisions would govern the sharing of certain information contained in permit applications and notifications for importations, interstate movements, or releases into the environment of regulated articles. The procedures would allow the Animal and Plant Health Inspection Service (APHIS) to share certain business information with State and Tribal governments without impairing our ability to protect confidential business information from disclosure. APHIS currently withholds such information when it shares applications with non-Federal Government agencies. This action would improve our collaborative and cooperative efforts with State and Tribal governments as well as improve the effectiveness of our notification and permitting procedures as APHIS continues to regulate certain genetically engineered organisms.

DATES: We will consider all comments that we receive on or before [Insert date 60 days after date of publication in Federal Register].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to
<http://www.regulations.gov/#!documentDetail;D=APHIS-2006-0124-0001>.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2006-0124, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2006-0124> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Ms. Chessa Huff-Woodard, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 146, Riverdale, MD 20737-1236; (301) 851-3943.

SUPPLEMENTARY INFORMATION:

Background

The Animal and Plant Health Inspection Service (APHIS) regulates the introduction (importation, interstate movement, or release into the environment) of organisms altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests under 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced

Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests" (referred to below as the regulations or as part 340). The regulations refer to such genetically engineered (GE) organisms and products as "regulated articles." The purpose of the regulations is to prevent the dissemination of plant pests.

With certain limited exceptions, the regulations prohibit the introduction (importation, interstate movement, or release into the environment) of any regulated article unless APHIS has issued a permit for the introduction in accordance with § 340.4, or unless APHIS has been notified in accordance with § 340.3 for certain GE plants that meet specified eligibility requirements and performance standards. Before APHIS authorizes the introduction, APHIS makes a determination on whether the actions under notification or permit are likely to result in the risk of introduction of a plant pest. In order to make that determination, APHIS requires applicants to provide essential information, some of which is designated by the applicant as confidential business information (CBI).

As provided in §§ 340.3 and 340.4, APHIS shares notifications and applications for permits for introductions, minus any information designated as confidential business information identified by the submitter, with State regulatory officials in the States of introduction. We now propose to share certain business information with State and Tribal regulatory officials. APHIS proposes to share certain business information only with those specific State or Tribal agencies that have legal jurisdiction over genetically engineered agricultural crops and/or products. No other State or Tribal agencies would have any access to the shared CBI. This information sharing would allow APHIS to share issues of concern with the officials of the State where the introduction is planned and would also enable the States to better review and comment on notifications and permits and provide information, advice, and recommendations to APHIS.

APHIS would also share certain business information in notifications and applications for permits with Tribal government officials when introductions of regulated articles are proposed for Tribal lands.

Permit applications, notifications, and other information submitted to APHIS under the regulations frequently contain business information designated by the submitter to be confidential in nature and marked as such on the submission. CBI is protected from mandatory public disclosure under the Freedom of Information Act (FOIA), exemption 4 (5 U.S.C. 552(b)(4)). Exemption 4 covers two broad categories of information in Federal agency records: (1) Trade secret information and (2) information that is commercial or financial, obtained from a person and privileged or confidential. It has been APHIS policy¹ not to release designated CBI to State or Tribal government officials. The APHIS FOIA Office oversees any information release requested under FOIA.

APHIS' notification and permit procedures require that if an applicant claims submitted information to be CBI, that information must be clearly designated as such. In accordance with the regulations and guidance documents,² persons submitting either notifications or permit applications by mail who believe their submission contains CBI must submit two copies, one with all CBI material clearly marked and another with all CBI material deleted. For submissions by means of ePermits, the applicant encloses CBI material within brackets and appropriate versions are automatically generated for State distribution with the designated CBI deleted.

APHIS may review the designated CBI material and may propose that the applicant make

¹ See 50 FR 38561-38563, "Policy Statement on the Protection of Privileged or Confidential Business Information" in the Federal Register September 23, 1985. The instructions for submitting designated CBI consistent with this policy are found in the BRS document titled "USDA-APHIS Biotechnology Regulatory Services User's Guide" (version 2/5/2008, on pp. 8-11). This information may be viewed on the Internet at http://www.aphis.usda.gov/brs/pdf/Doc_Prep_Guidance.pdf or obtained from the person listed under FOR FURTHER INFORMATION CONTACT.

² 7 CFR 340.4(a) and "USDA-APHIS Biotechnology Regulatory Services User's Guide."

changes to the designated CBI material if APHIS determines that some of the designated CBI material is in fact not CBI material and should not be designated as CBI.

Currently, APHIS shares only “CBI-deleted” copies of notification or permit submissions with appropriate State or Tribal regulatory officials. State and Tribal officials may provide comments on the applications sent them, but are not required to do so.

Historically, applicants have claimed a wide range of information that they have to submit to APHIS as being CBI. For example, applicants have claimed the exact location of an introduction (facility address or GPS coordinates for an environmental release) as CBI. Applicants have also claimed confidentiality for genes, the gene donor, production details, and particular details about phenotype of the regulated article. Permit applications generally have more material designated as CBI than do notifications because permit applications have more detailed descriptions of the phenotype of the regulated article (described in § 340.4(b)(5)) than do notifications (described in § 340.3(d)(2)). Permit applications also contain a description of the methods for confinement of the regulated article during the introduction. Other material often claimed as CBI in permit applications specifically for release into the environment includes the purpose of the environmental release, descriptions of the release, proposed procedures and confinement methods, and other safeguards and mitigation measures to prevent dissemination or persistence following the environmental release.

Currently, if a State or Tribal official desires to see information from notification or permit applications, acknowledged notifications, or issued permits and that information has been designated as CBI by the applicant, the official would need to contact the applicant for the information. However, APHIS has not always withheld designated CBI from State or Tribal regulatory officials. Around 1988, APHIS began sharing certain business information

designated by submitters as CBI with State authorities if the State's attorney general submitted a letter to APHIS agreeing to protect the confidentiality of the information to be shared. Only a few States were authorized to receive designated CBI from APHIS using this mechanism. In 2001, this policy was discontinued because of concerns that sharing designated CBI with States could be deemed to constitute a waiver of the applicable exemption from disclosure under FOIA. During the period when we shared designated CBI with the States, the only shared records were paper documents, and there were no reports that a State's process to protect designated CBI shared with them by APHIS had failed, or that any such business information had been released to unauthorized persons.

On June 7, 2004, APHIS convened a meeting with the National Association of State Directors of Agriculture (NASDA). One of the main purposes of the meeting was to evaluate the quality of interactions between APHIS and State governments, especially with respect to biotechnology issues. At that meeting, State officials expressed the view that cooperation and collaboration between APHIS and the States in regulatory activities for agricultural biotechnology may not be as effective as possible because information withheld as CBI from notification and permit applications often appeared to be important to the State's review. State officials expressed concern about the adequacy of reviews conducted when important information was not available to them.

The discussions regarding sharing of designated CBI information initiated at the 2004 NASDA meeting have continued over time, along with discussions covering a range of regulatory activities and compliance and enforcement issues arising within agricultural biotechnology. These discussions focused on methods of sharing designated CBI with the States that would be consistent with the ability of the States to prevent disclosure under State FOIA

laws and other applicable disclosure statutes or policies of the States. As a result of these discussions, APHIS has developed this proposed rule to allow the sharing of certain business information desired by State and Tribal government authorities.

Purpose and Effects of the Proposed Rule

This proposed rule would establish a mechanism for APHIS to share certain information designated as CBI with State and Tribal government agencies. This sharing would provide benefits to APHIS, and to the States and Tribal governments, and strengthen the relationship between the Federal and other governments. For APHIS, a provision to share certain business information will benefit compliance activities, improve the efficiency of the permit and notification processes, and facilitate inspections by State regulators under the supervision of APHIS. For the State and Tribal governments, the proposed changes would enhance participation in the assessment process and encourage these entities to be more fully informed and involved. The proposed sharing of certain business information would be accomplished without compromising the protection afforded CBI under FOIA's Exemption 4.

Benefits to APHIS' Emergency Response Activities

Sharing certain business information with State and Tribal governments would support better contingency planning and disaster responses. In the event of a local emergency, such as a hurricane, tornado, or flooding, there may be a need to assess and potentially remediate locations where regulated articles were present as part of an environmental release or were in a containment facility that became damaged. In these events, State and Tribal government officials in proximity to the area of concern may be better prepared to respond to this situation if they already have knowledge of the regulated article, the location of the site, and the identities of the personnel responsible for the site. Because such business information is often designated as

CBI, and if APHIS could not share certain CBI with the appropriate State and Tribal authorities, participation of the State or Tribes may be hampered, making appropriate remedial action more difficult and a timely response less likely.

Improved Efficiency of Permits and Notification Process

The ability to share CBI would aid APHIS and State and Tribal governments by improving the efficiency of the notification and permitting processes. The proposed sharing of certain business information would help avoid the delays that frequently occur in the current APHIS permitting and notification process. These delays may occur when a State or Tribal government decides it must ask the developer of the regulated article for business information about a proposed introduction of the regulated article. The business information requested is often part of the CBI information the developer submitted in its application to APHIS, but deleted when the application was forwarded to the State or Tribal government. From previous experience, APHIS understands that such requests by State agencies or Tribal officials for certain business information from applicants can sometimes be lengthy processes. Because the applicant may not have a routine procedure to respond to a State or Tribal agency, requests for information may not be processed in a timely manner by the applicant.

State and Tribal Participation in the Assessment and Permitting Process

Under this proposed rule, only the appropriate State and Tribal agencies would be able to review the conditions assigned by APHIS for introduction of a regulated article and also to confer with APHIS on any additional issues related to a permit or notification. For example, feedback provided by State and Tribal agencies about the site of an environmental release or nearby areas may help APHIS to further review assigned confinement conditions. The goal of these conditions is to prevent possible unauthorized dissemination of plant pests. State and

Tribal agencies may wish to discuss with APHIS any information regarding activities, commerce, and traffic in the area of an environmental release. Such local information may further inform APHIS about appropriate confinement conditions for an environmental release, ensure better compliance with the conditions of the permit, or help the applicant meet the performance standards for notifications.

In some cases, a State or Tribal regulatory official could assess citizen, consumer, or grower concerns about introductions at certain locations, and then convey these issues to APHIS. In these situations, APHIS would receive valuable inputs from the State and Tribal agencies that would be used to confirm confinement protocols and advise product developers. Yet other activities might be facilitated by sharing of certain business information about the regulated crop and its planting location. In other cases, by working closely with State agencies or Tribal nations in possession of authorized shared CBI, APHIS may obtain certain information about environmental releases to assist in complying with other Federal statutes, e.g., the Endangered Species Act.

This proposal would improve Federal transparency because the appropriate State and Tribal government agencies receiving certain business information from APHIS would be better informed about introductions within their jurisdictions. Furthermore, when the State or Tribal agencies have accurate and detailed information about introductions, they would be better prepared to explain to their citizens the proposed introduction of genetically engineered organisms at publicly undisclosed sites within their jurisdiction. Consequently, the proposed sharing could increase public confidence in Federal, State and Tribal oversight of introductions of regulated articles.

Facilitating State Agency Inspections of Release Sites

Recent APHIS experience has demonstrated the value of sharing certain business information with States and Tribal governments. In 2005, APHIS initiated an ongoing pilot inspection project with some State plant regulatory agencies. APHIS evaluated whether State inspectors could supplement APHIS officers by performing inspections of environmental release sites for regulated articles. For this pilot project, State inspectors received the same training as APHIS officers, and then were to conduct inspections on behalf of APHIS. In the course of this pilot project, APHIS' lack of authority to share CBI with State cooperators prevented full employment of State inspectors to accomplish APHIS' regulatory objectives. Because CBI-deleted documents may not contain certain business information crucial to inspections, such as the contact information for the applicant's site cooperator, or the exact location of the environmental release, State inspectors had to obtain this information from the applicant. This extra step added time and uncertainty to the necessary inspections, which are scheduled to correspond with the timing of certain biological and business activities related to the regulated article (pollination, harvest, etc.). This step of requesting information from the applicant may cause unacceptable delays that potentially interfere with timely completion of inspections.

Balancing the Benefits of Information Sharing and Confidentiality and Privacy Interests

Overall, APHIS anticipates that this new sharing activity for certain business information would benefit APHIS' compliance activities, enhance the effectiveness and efficiency of the permitting process, and allow the fullest use of State-employed inspectors. Increased participation by the States and Tribal governments in the permitting and notification processes would allow them to engage APHIS in mutually beneficial and constructive collaborations. By informing these governments about introductions into their State or Tribal lands, the sharing of

certain business information will initiate a new level of transparency for APHIS with State and Tribal government stakeholders and enhance their ability to represent the interests of the public they represent

Despite the benefits of this proposed activity, APHIS is required to choose a procedure that does not publicly disclose CBI submitted by the applicant. Except for the brief period 1988-2001, APHIS' communication with the States and Tribal governments generally had the same status as communication with any member of the public. In accordance with 5 U.S.C. 552(a)(3)(A), any record of the Agency that is disclosed in an authorized manner to any member of the public is available for disclosure to all members of the public.

There are times when public disclosure of information would undermine legitimate private rights and governmental responsibilities. As discussed above, FOIA Exemption 4 (5 U.S.C. 552(b)(4)) states that disclosure requirements do not apply to "trade secrets and commercial or financial information obtained from a person and privileged or confidential." This exemption applies to all notification and permit information that applicants designate as CBI and that APHIS accepts and treats as CBI as required by applicable Federal laws. Another FOIA exemption that is applicable to some or all of this material is Exemption 5 (5 U.S.C. 552(b)(5)), "inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency." To the extent that applicant designated CBI is contained in APHIS inter-agency or intra-agency memorandums or letters, APHIS will review such documents to determine if such CBI material should be withheld pursuant to the applicable Federal laws. Exemption 6 (5 U.S.C. 552(b)(6)), "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy," would also apply in some cases where the disclosed information

would, for example, lead to the identity of the landowner or leaseholder where the field test was being conducted.

Our proposed provisions for the sharing of certain business information would include a statement that the appropriate State and Tribal agencies receiving the shared information are not members of the public for purposes of disclosure of designated CBI submitted to APHIS by notification or permit applicants as required by part 340. Accordingly, disclosure of the authorized information by APHIS to the State or Tribal government would not constitute a waiver of any FOIA exemption protection.

Mechanisms for Safeguarding Shared Information

APHIS proposes to establish a new § 340.10 that would contain requirements for safeguarding shared business information and would also describe what types of CBI could be shared with States and Tribal governments. We propose that if any of this information is to be retained by the State or Tribal governments, only paper copies would be authorized for retention. Currently, APHIS is examining various electronic options to share certain business information, but a method for doing so has not been selected. We considered allowing regulators in authorized States and Tribal governments to share certain business information that was downloaded to a secure APHIS server, and then granting access to the authorized government entities. However, providing a new and separate secure system was not likely to be economically viable for APHIS. Although secured access to electronic records containing certain business information is not possible at this time, APHIS will continue to explore the possibility of sharing this information with authorized State or Tribal government officials by this means in the future. If APHIS finds an electronic means to share certain business information with these agencies, APHIS will deploy a system that conforms to all appropriate

Federal cyber security requirements and ensures the confidentiality and integrity of the CBI data. Also, as part of the implementation plan for this rule, APHIS will survey State and Tribal government agencies 6 and 12 months after initiating that system to determine whether the electronic means of sharing CBI meets the needs of the appropriate State and Tribal regulatory officials.

The Administrator may authorize sharing of information under proposed § 340.10 provided that five conditions are met by the appropriate State or Tribal government authority desiring the shared information, as stated in a written agreement between the State or Tribal governments and APHIS. Proposed § 340.10 (a)(1) would require the State or Tribal government officials to state their authority to protect from public disclosure permit and compliance information that has been designated CBI in the written agreement. Based on our preliminary review of State authorities, APHIS realizes that only some States have the legal authority to protect the specified types of business information from public disclosures. For example, the four States currently participating in the APHIS pilot program in 2009 -- Arkansas, Florida, Kansas, and North Carolina -- were able to provide letters indicating that shared confidential business information could be protected if disclosed to State inspectors by the applicant. However, we particularly invite comments on whether limits to statutory authority in any State would preclude its participation in the proposed information sharing program.

Proposed § 340.10(a)(2) would require the State or Tribal government to have in place suitable procedures to ensure the security of the shared confidential business information and to specify and restrict which specific State or Tribal agency or agencies and their respective officials are allowed access to it. These officials would be required to complete the same annual “Confidential Business Information and Records Management” training that APHIS requires of

employees handling CBI. State and Tribal procedures would have to be equivalent to those currently used by APHIS, which are specified in APHIS' "Policy Statement on the Protection of Privileged or Confidential Business Information" cited above. At this time, APHIS would not allow State or Tribal agencies to store in electronic form or otherwise create any records of any CBI received from APHIS. Nevertheless, APHIS is exploring and seeking input on sharing certain business information with State and Tribal government agencies by electronic means. This issue is discussed further in the first paragraph of this section above.

The goal of these security measures would be to safeguard documents containing information disclosed under the proposed provisions, i.e., to account for the location of documents at all times, control access to documents, and provide for secure transmittal, destruction, or return of documents to APHIS. If State or Tribal agencies employ methods equivalent to those used by APHIS, we are confident that they can review this information while effectively maintaining document security. Adaptations of these procedures that achieve an equivalent effect would be specified in the required written agreement between APHIS and a State or Tribal government agency.

Proposed § 340.10(a)(3) would require a commitment in the written agreement between APHIS and the State or Tribal government not to disclose CBI without the written permission of the submitter or written confirmation from APHIS that the information is no longer considered CBI as determined by APHIS pursuant to the applicable Federal laws. Proposed § 340.10(a)(4) would require a commitment in the written agreement by the State or Tribal government that all persons authorized to have access to CBI provided by APHIS will be trained by the State or Tribal authority on how to maintain the security of the shared CBI before having access to it. APHIS would provide the content of the required training.

This training requirement would also apply to situations where a State or Tribal authority needs to share certain business information with State or Tribal employees who are not regulatory officials (such as faculty of State universities) and APHIS agrees to allow the non-regulatory State or Tribal employees access to the shared CBI. Such persons would need training to protect this information from disclosure and in these cases, the parties would need to establish additional safeguards within the written agreement before those non-regulatory State or Tribal employees were allowed access to the shared CBI. For example, the State or Tribal authority would have to agree to appoint regulatory officials to oversee confidentiality rules and responsibilities for safeguarding business information shared with these other employees.

Each government agency entering into a written agreement with APHIS to receive certain business information would be obligated under the terms of the written agreement to safeguard the entrusted information. If a State or Tribal government intentionally or even unintentionally releases certain authorized business information, APHIS would make a determination of whether or not to immediately void the written agreement and revoke the agency's privilege to receive future authorized information or whether to impose appropriate corrective actions, conditions, and/or requirements into the written agreement for the agency. Also, individuals who release protected information may be subject to penalties under applicable State or Tribal laws for the protection of trade secrets and confidential business information.

The final provision for the written agreement, proposed § 340.10(a)(5), would require inclusion of other needed terms agreed to by APHIS and the State or Tribal government regarding the shared information. This provision could take into account and incorporate administrative procedures or authorities that are unique to a State or Tribe.

Description of Information to be Shared

Proposed § 340.10(b) describes the types of CBI from notifications and permit applications, acknowledged notifications, or issued permits that APHIS proposes to share with States and Tribal governments. APHIS developed these information categories based on our experience working with States and Tribes and our observations of what types of information prevented optimal cooperation from States or Tribes in application review, inspection, and other activities under the regulations. APHIS also used responses to a questionnaire developed and distributed by NASDA that identified information needs perceived by State regulatory officials. Respondents identified the following information as useful during their State review: Information about the regulated article and its phenotype, the location and contact information of any cooperators for the introduction, activity dates during the introduction (e.g., planting, inoculation, harvest dates for environmental releases), and protocols used during the introduction.

When information sharing is requested by the State or Tribal government agency, APHIS proposes to share:

- Information about the regulated article(s) being used during the introduction, including information in the notification or permit application, the acknowledged notification, or the issued permit regarding the phenotypic designation, and the phenotypic description of anticipated expression of the altered genetic material in the regulated article compared to the expression in the non-modified parental organism;
- The location(s) of the introduction identified by the applicant within the territory of the State or Tribal nation of the requester, including the cooperator's address; GPS

coordinates corresponding to multiple sites within the particular State or Tribe; and the number of acres for an environmental release;

- The dates of activity during the environmental release, including planting dates and termination dates for the release;
- The methods of confinement as they are approved by APHIS at the time of application (for permits, APHIS would share the mandatory and supplemental conditions required by APHIS and those cited in the permit application; for notifications, APHIS would provide design protocols for the regulated articles); and
- The name and contact information for the responsible person for the introduction.

Related Changes in Part 340

The regulations in § 340.4(b) and (c) currently state that when APHIS determines that a permit application is complete, we will submit to the State department of agriculture of the State where an introduction is planned a copy of the initial review along with the application marked "CBI Deleted" or "No CBI" for State notification and review. Because proposed § 340.10 would allow us to share CBI with the appropriate State or Tribal officials, we would amend § 340.4(b) and (c) to state that when an application contains designated CBI, the State or Tribal government will be provided a "CBI deleted" copy of the application unless the disclosure of certain business information to the State or Tribal government has been authorized in accordance with § 340.10 and is requested by the State or Tribal government.

The current regulations identify the procedures for a permit applicant to identify and mark CBI information in § 340.4(a). CBI information submitted in notification applications is identified and marked exactly the same way as such information is marked and identified in permit applications. However, APHIS neglected to include parallel language in the notifications

section at the time the notifications procedure was added to part 340. APHIS proposes to take this opportunity to remedy that oversight by adding a reference in § 340.3(d) for submission of CBI in notifications. The section “Procedural requirements for notifying APHIS” will contain parallel language to that in § 340.4(a) addressing CBI in permit applications.

Executive Orders 12866 and 13563 and Regulatory Flexibility Act.

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

APHIS has prepared an economic analysis for this proposed rule, which is set out below. The analysis provides a cost-benefit analysis, as required by Executive Order 12866, and an analysis of the potential economic effects of this proposed rule on small entities, as required by the Regulatory Flexibility Act.

This proposal would amend APHIS’ part 340 regulations regarding regulated articles to add provisions concerning the sharing of certain business information but only with certain officials of State and Tribal government agencies. The proposed provisions would create mechanisms for sharing certain business information contained in permit applications and notifications that are submitted to APHIS under the regulations, while continuing to allow APHIS to protect the confidentiality of the information.

Benefits

The benefits of the proposed rule include improving the effectiveness and efficiency of the notification and permitting processes of part 340. At the same time, the rule will enhance and maintain the rigorous regulation of regulated articles. Specifically, State and Tribal government officials could receive information from APHIS that APHIS would withhold as CBI under current procedures and that applicants may choose not to disclose if requested directly by States or Tribes. This would allow those State and Tribal government officials to provide more timely and more pertinent information to APHIS regarding site-specific issues related to notifications or permits. Although APHIS does not envision any efficiencies gained from reduced paper handling, efficiencies will derive from fewer days required for APHIS to await State or Tribal responses to new permit and notification applications. The process and rationale for APHIS' decisions regarding introductions (e.g., assignment of permit conditions for specific environmental releases, importations and interstate movements) would be improved and would be more transparent to State and Tribal governments because they would also have certain business information APHIS used in its decisionmaking process. In addition, new collaborations with the States and Tribes on permit issues would be beneficial to the authorized State and Tribal authorities as well as to APHIS. A current pilot program that authorizes State inspectors to review compliance information for approved environmental release sites would be facilitated by making available information about regulated articles and the respective environmental release sites. Also, future compliance incidents could be assessed and remediated under APHIS direction by State employees, if provided with appropriate information about permits or notifications. By facilitating these actions, APHIS' effectiveness in the continuing and evolving

oversight of regulated articles and their potential attainment of non-regulated status would be enhanced.

Costs

There would be minimal costs to the States and Tribes associated with sharing certain business information between these agencies and APHIS. Costs would be the resources required to draft and sign a written agreement, and the resources it would take to share the information, provide for the appropriate training of those State or Tribal officials that would have access to the CBI, and provide the appropriate mechanisms for safeguarding the shared CBI. State agencies and Tribal officials not currently equipped to handle CBI would incur costs of updating or equipping their facilities with secure filing systems, provided that they entered into a written agreement with APHIS. Because only the storage of paper documents would be authorized, not the storage of electronic documents, no computer security costs would be incurred. There would be no cost to the biotechnology industry as we expect the required measures will protect sensitive information. Costs to assess the business information proposed for sharing by APHIS are discretionary; if the information is not requested, APHIS would not provide it to the States and Tribal governments.

The cost to APHIS would consist mainly of salary for staff to implement the procedures and to carry them out on a continuing basis. This should entail less than one full-time staff year during implementation, and decrease later as the procedures become routine for APHIS, States, and Tribes. We expect the benefits of sharing certain business information with State and Tribal agencies would outweigh the costs to the Federal government. The proposed rule would add transparency to the APHIS review process, as State and Tribal officials would have additional information about introductions conducted within their jurisdictions. Also, State citizens and

Tribal members would have greater confidence in their regulatory officials and their ability to review permit and notification applications, and APHIS would have an additional means to strengthen its regulatory effort through improved process efficiency and effectiveness.

There are no unavoidable costs for States and Tribes under either the current application review process or the CBI sharing provisions that would be added by this proposed rule because APHIS does not require States or Tribes to reply to permit and notification review information shared with them. However, the States and Tribes involved have indicated they value the opportunity to do so. Frequently, information provided to APHIS during these reviews has allowed us to improve permit conditions and reduce risks, or to forestall operational or administrative problems that might have arisen during a permit period due to local conditions that State or Tribal officials explained to APHIS. Permit and notification review also allows States to better plan their logistics and workloads from year to year. If CBI information is shared as described in this proposal, States and Tribes would know more about the exact location of planned introductions, the methods for confinement of the regulated article, and other planned safeguards and mitigation measures. This would allow States to do better advance planning of the activities and movements of their inspectors who inspect and monitor release sites in accordance with a Memorandum of Understanding with APHIS. It would also allow them to be better prepared for responses during emergency situations, e.g., tornadoes or floods, because they would know well in advance what locations they might have to visit to assess possible releases and what types of confinement and mitigation systems they will encounter at the sites.

Alternatives Considered

APHIS considered a “no action” alternative under which we would continue to delete CBI information from notification and permit applications, and then share only the CBI-deleted

documents with States and Tribal governments. This alternative would avoid the implementation costs identified for this proposal, but would not accrue any of the benefits identified for sharing certain business information. The no action alternative could also result in continuing costs to the Federal government through reduced effectiveness of the regulatory program.

APHIS also considered various additional alternatives for how APHIS could share business information with the State or Tribal governments. These alternatives are discussed in detail above under the heading “Mechanisms for Safeguarding Shared Information.”

In the selected alternative, APHIS proposes to allow sharing of paper documents by only certain States or Tribal governments which are capable of preventing disclosure of such paper records to the public. These States or Tribal governments must also be able to comply with the requirements set forth in the proposed rule.

Effects on Small Entities

APHIS has not identified any private entities, large or small, that would be affected by this proposed rule. APHIS would share certain business information from both large and small entities with State agencies and Tribal officials, as the written agreement would provide. There would be no direct economic effect on entities submitting CBI. Some such entities might accrue minor savings in time they currently spend responding to State or Tribes’ requests for information, if States or Tribes instead obtain the information through APHIS.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) No State or local laws or regulations will be preempted by this rule; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule. State or Tribal agencies must follow their respective State or Tribal laws regarding disclosure of information, and a State or Tribe with a law that precludes it from signing a written nondisclosure agreement with APHIS in accordance with proposed § 340.10 would not be able to participate in the business information sharing that would be authorized by this proposed rule.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this rule will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

National Environmental Policy Act

APHIS, in compliance with the National Environmental Policy Act (NEPA) of 1969, as amended (42 U.S.C. 4321 et seq.), categorically excluded the proposed sharing of CBI with States and Tribes consistent with the USDA Departmental NEPA implementing regulations specific to categorical exclusions for the implementation of a procedural policy (7 CFR 1b.3(1)).

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. APHIS-2006-0124. Please send a copy of your comments to: (1) Docket No. APHIS-2006-0124, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238, and (2) Clearance Officer, OCIO, USDA, room 404-W, 14th Street and Independence Avenue SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

This proposed rule contains certain information collection and recordkeeping requirements that would apply to regulatory officials of the States that receive APHIS submissions of notifications and permits for importations, interstate movements, and environmental releases that occur within the State or Tribal lands. The limited information presently shared with the States is authorized under §§ 340.3(e) and 340.4(b). The majority of the proposed requirements would apply to persons engaged in regulatory activities of regulated articles in the States or on Tribal Lands. The reporting burden for these officials under the proposed rule would be similar to the burden under the current regulations, except in those cases in which the State or Tribe desired more information about the details of introductions in the States or Tribes beyond that which they have historically been provided. Thus, all additional information received would be elective. The information is shared because APHIS desires to

have States and Tribes better informed about introductions that occur in the States or Tribes, and because the States or Tribes may be able to provide additional assistance to APHIS in issuing the permit or acknowledging the notification. In some cases, the additional information would be shared with the State's or Tribe's inspectors when they are working with APHIS to conduct inspections, or when APHIS requests a State or a Tribe's assistance to aid with compliance and mitigation efforts. Major emergencies sometimes threaten confinement of a regulated article, and APHIS may require assistance in these circumstances.

Under proposed §§ 340.3(d)(2)(vi) and 340.4(b) and (c), State or Tribe officials would have available additional information to complete their reviews of APHIS notifications and permits. However, responses to APHIS would remain voluntary, as they are presently under § 340.3(e). Additional reading, assessment, and review writing may be required if the official desires to provide comments and information to APHIS on the business information shared under this proposed rule.

For those States or Tribes whose statutes authorize keeping business information confidential, and which have signed agreements with APHIS to protect the authorized data, additional recordkeeping requirements would be needed. As noted in the analysis of costs, safeguarding the information would require expenses of time and resources to update or establish approved systems to store certain business information as well as training the regulatory officials that would have access to the CBI. Some States may already have an approved mechanism for storing this information, and no additional burden would be imposed on them.

One goal in proposing this rule is to create an efficient and streamlined system for information sharing with the State and Tribal governments and to ensure that the review process is conducted in a timely and effective manner. Permit applications for environmental releases

may take up to 120 days to assess and review before APHIS decides to either issue or deny a permit, while movements (importations and interstate movements) alone may take up to 60 days prior to a decision. Notifications for environmental releases may take up to 30 days to assess and review before APHIS decides to either acknowledge or deny the notification, movements, importations, or interstate movements under notifications may require 10 days after application for an APHIS decision regarding them. Certain business information may be provided by APHIS directly to the States or Tribal agencies after a written agreement is in effect, replacing the necessity that information useful to the States or Tribal governments be provided by the applicant. Based on this sharing, the States and Tribal governments would review and provide comment to APHIS, and APHIS could complete the review process for permits and notifications in a timely manner.

We are soliciting comments from the public (as well as the affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological

collection techniques or other forms of information technology; e.g., permitting electronic submission of responses).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 8 hours for each written nondisclosure agreement signed by a State or Tribal government official and APHIS. Actual review by States and Tribal authorities of CBI documents shared under the proposed rule is estimated to average 2 hours per permit and notification application. This is a decrease from the current review practice which can take up to 2 weeks when a State representative must obtain the business information directly from the applicant.

Respondents: Approximately 49 States or Territories, including the Northern Mariana Islands, Guam, Puerto Rico, and the U.S. Virgin Islands, as well as approximately 2 Tribes and 69 unique officials in these entities.

Estimated annual number of responses per respondent: Only one in the first year, then fewer. The written nondisclosure agreement between APHIS and the State or Tribal government is the primary new information collection imposed by this rule. Such agreements would presumably be signed in the first year of implementation, and be revised or renewed infrequently after that. Responses by States to the specific, individual permit applications or notifications they review already occur, and will continue to do so, and thus are not a new information collection.

Estimated annual number of responses: 51 or fewer written agreements.

Estimated total annual burden on respondents: 408 hours, declining over time.

Copies of this information collection can be obtained from Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851-2908.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this proposed rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851-2908.

List of Subjects in 7 CFR Part 340

Administrative practice and procedure, Biotechnology, Genetic engineering, Imports, Packaging and containers, Plant diseases and pests, Transportation.

Accordingly, we propose to amend 7 CFR part 340 as follows:

PART 340--INTRODUCTION OF ORGANISMS AND PRODUCTS ALTERED OR PRODUCED THROUGH GENETIC ENGINEERING WHICH ARE PLANT PESTS OR WHICH THERE IS REASON TO BELIEVE ARE PLANT PESTS

1. The authority citation for part 340 continues to read as follows:

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

2. In § 340.3, a new paragraph (d)(2)(vi) is added to read as follows:

§ 340.3 Notification for the introduction of certain regulated articles.⁵

* * * * *

⁵ APHIS may issue guidelines regarding scientific procedures, practices, or protocols which it has found acceptable in making various determinations under the regulations. A person may follow an APHIS guideline or follow different procedures, practices, or protocols. When different procedures, practices, or protocols are followed, a person may, but is not required to, discuss the matter in advance with APHIS to help ensure that the procedures, practices, or protocols to be followed will be acceptable to APHIS.

(d) * * *

(2) * * *

(vi) If there are portions of the notification deemed to contain trade secret or confidential business information (CBI), and if submitted through ePermits, then all information entered into the forms that is designated CBI should be enclosed in brackets and all subsequent copies will be automatically labeled with appropriate CBI notations. If submitted on paper, two copies of the written notification shall be submitted. On one copy, each page of the application containing trade secret or CBI should be marked “CBI Copy.” In addition, those portions of the notifications which are deemed “CBI” shall be so designated. The second copy shall have all such CBI deleted and shall be marked on each page of the application where CBI was deleted, “CBI Deleted.” If a notification does not contain CBI, then the first page of both copies shall be marked “No CBI.” When it is determined that a notification is complete, APHIS shall submit to the State department of agriculture of the State or the appropriate Tribal official of the Tribal land where the introduction is planned a copy of the notification for State or Tribal notification and review. When the application contains certain business information, the State or Tribal government will be provided a CBI deleted copy of the notification unless the disclosure of certain business information to the State or Tribal government has been authorized in accordance with § 340.10.

* * * * *

3. Section 340.4 is amended as follows:

a. In paragraph (b), introductory text, by removing the sixth sentence and by adding in its place two new sentences to read as set forth below.

b. In paragraph (c), introductory text, by removing the last sentence and by adding in its place two new sentences to read as set forth below.

§ 340.4 Permits for the introduction of a regulated article.⁶

* * * *

(b) * * * When it is determined that an application is complete, APHIS shall submit to the State department of agriculture of the State or the appropriate Tribal official of the Tribal land where the release is planned a copy of the initial review and a copy of the application for State or Tribal notification and review. When the application contains confidential business information (CBI), the State or Tribal government will be provided a CBI deleted copy of the application unless the disclosure of certain business information to the State or Tribal government has been authorized in accordance with § 340.10. * * *

* * * *

(c) * * * When it is determined that an application is complete, APHIS shall submit to the State department of agriculture of the State of destination or to the appropriate Tribal official of the Tribal land of destination of the regulated article a copy of the initial review and a copy of the application for State or Tribal notification and review. When the application contains confidential business information (CBI), the State or Tribal government will be provided a CBI deleted copy of the application unless the disclosure of certain business information to the State has been authorized in accordance with § 340.10.

* * * *

4. A new § 340.10 is added to read as follows:

§ 340.10 Communications with State and Tribal government agencies.

⁶ See footnote 5 in § 340.3.

The Administrator may authorize in accordance with the provisions of this section the disclosure of certain business information (CBI) to State or Tribal government agencies that has been submitted to APHIS or incorporated into Agency-prepared records.

(a) Certain business information submitted to APHIS in notifications and applications for permits under this part may be disclosed to State or Tribal government agencies provided that the State or Tribal government agency has entered into a written agreement with APHIS that includes:

(1) A statement establishing the State's or Tribe's authority to protect certain business information from public disclosure;

(2) A statement by the State or Tribal government agency that it has suitable procedures in place to ensure the security of the business information, and the means to specify and restrict their respective officials allowed access to such information. Such procedures must be equivalent to those specified in APHIS' policy¹⁴ on the protection of privileged or confidential business information;

(3) A statement that the State or Tribal government agency will not disclose any business information provided by APHIS without the written permission of the submitter of the information or written confirmation by APHIS that the information no longer has confidential status;

¹⁴ APHIS' "Policy Statement on the Protection of Privileged or Confidential Business Information" may be viewed on the APHIS Web site at http://www.aphis.usda.gov/animal_health/vet_biologics/publications/pel_1_2.pdf. The instructions for submitting CBI consistent with this policy are found in the BRS document titled "USDA-APHIS Biotechnology Regulatory Services User's Guide"(version 2/5/2008) and information may be viewed on the Internet at http://www.aphis.usda.gov/brs/pdf/Doc_Prep_Guidance.pdf or obtained from the person listed under FOR FURTHER INFORMATION CONTACT.

(4) A statement that all persons with access to business information provided by APHIS will be trained by the State or Tribal authority on how to maintain the security of the shared APHIS documents before having access to the CBI;

(5) Any other terms as agreed to by APHIS and the State or Tribal government agency.

(b) The “certain business information” that APHIS may authorize to be shared under paragraph (a) of this section may include information about the regulated article, including details about the phenotype as provided by the applicant; the site(s) of the introduction including provision of accurate details of the location, acreage (for environmental releases), and purpose of the introduction if provided; dates of activities, including proposed planting and termination dates for the regulated article, actual dates when available; methods of confinement, including design protocols if available, and description of disposition if provided; and site cooperator, including contact information for the responsible person or cooperator, depending upon what information the applicant has provided to APHIS. APHIS intends that the disclosure of information will be for the purpose of facilitating the State or Tribal agency review. In addition, the exchange of information may also be made in certain emergency situations with States or Tribal government agencies to support better disaster responses and maintain confinement of regulated articles. Also, information sharing will help facilitate participation in the inspection and compliance programs established between the States and Tribes and APHIS under specific agreements.

(c) Information APHIS discloses under this section is not a disclosure of information to the public. Disclosures made under this section do not waive any FOIA exemption protection.

Done in Washington, DC, this 20th day of February 2013 .

Rebecca Blue

Deputy Under Secretary for Marketing and Regulatory Programs.

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